11. (Currently Amended) A method of treating a patient [undergoing vitamin D therapy] for secondary hyperparathyroidism using a vitamin D therapy, [wherein the] comprising administering an initial dose of vitamin D [administered] to the patient wherein the initial dose of vitamin D is about patient baseline parathyroid hormone/80 (bPTH/80) and bPTH is the baseline PTH for the patient.

12. (Currently Amended) A method of determining the initial dose of a vitamin D compound using a zero-intercept linear regression model [to determine the initial dose of a vitamin D compound].

13. (Currently Amended) A method of treating a patient undergoing vitamin D therapy for [[ESRD]] end stage renal disease wherein a zero-intercept regression model is used to determine the initial dose of the vitamin D compound.

14. (Currently Amended) The method of claim 13, wherein the vitamin D therapy [[the vitamin D compound]] results in the prevention or treatment of renal osteodystrophy or secondary hyperparathyroidism.

15. (Original) A method of claim 8 wherein the initial dose is at least 1 mcg.

16. (New) The method of claim 13, wherein the vitamin D therapy does not increase the incidence of hypercalcemia.

Remarks

This Amendment and Response is in reply to the Office Action mailed May 5, 2005 in the subject application.

Claims 1-16 are pending; with claim 16 being newly added.

Rejections under 35 USC 112, paragraph 2

Claims 1-15 have been rejected in the Office Action for indefiniteness for failure to particularly point out and distinctly claim the subject matter Applicants consider to be their invention.

As indicated above, several of these claims have been amended along the lines suggested by the examiner, though Applicants disagree that the claims as originally presented were indefinite. Other clarifying amendments were made to the claims. No new subject matter was introduced by any of these amendments.

Applicants particularly note that the expression "bPTH/80" would be clear to those skilled in the art, even if the examiner was confused by the terminology, to mean baseline PTH **divided by** 80, ***not*** baseline PTH equals 80, as the examiner has suggested.

With respect to the examiner's rejection of claims 11, 12 and 14, the Office Action incorrectly states that these claims "depend directly or indirectly from claim 7." A careful review of these claims establishes that these are independent claims; they do not in fact depend from claim 7 or any other claim. Hence the rationale offered in the Office Action for the indefiniteness rejection does not make sense as to these claims. Therefore, this rejection is improper and should be withdrawn.

Prior Art Rejections

Claims 1 and 2 stand rejected as anticipated by Cummings (US 5891868). The Office Action states that Cummings teaches the various steps of Applicants' claimed invention.

Applicants strongly disagree.

A careful reading of the claims in the subject application indicates that the Cummings patent is irrelevant to the patentability of Applicants' invention. Each of the independent claims (as amended above) makes this plain. For example, claim 1 begins with a preamble, which states:

1. "A method of determining the initial dose of a vitamin D compound for the treatment of secondary hyperparathyroidism and renal osteodystrophy without increasing the incidence of hypercalcemia..."

No one skilled in the art would read Cummings to teach anything about a method **for determining the initial dose of a Vitamin D compound**. Instead, it is absolutely clear that Cummings relates to "methods for treating physical conditions resulting from postmenopausal estrogen decline in a postmenopausal subject." (See the abstract). Moreover, Column 4, lines 1-10 of Cummings state:

> "The present inventors have also unexpected discovered that the treatment of physical conditions resulting from estrogen decline can be affected by ultra low doses of estrogen without the need for administration of progestin. "

Cummings does nothing more than make reference to following serum Vitamin D in the patients who were given multi vitamins containing Vitamin d in order to identify risks bone fractures. The examiner's attention is drawn to Cummings at column 3, lines 35-45, and especially lines 43-45, which state:

> "In addition, low serum levels of 1,25 (OH) 2 Vitamin D levels also leads to increased risk of hip fractures."

With respect to other independent claims, Applicants also disagree that Cummings provides any relevant teaching for "treatments of secondary hyperparathyroidism and renal dystrophy without increasing the incidence of hypercalcemia" (claim 6), method of treating elevated PTH in a patient commencing treatment for end stage renal disease" (claim 7), "method of treating a patient for end stage renal disease using a vitamin D therapy (claim 10).

The rejection of Applicants' claimed invention over Cummings is improper and should be withdrawn.

Claims 1-15 stand rejected as obvious over the combined teachings of Cummings and Knutson (U.S. 5602116).

As indicated above, Cummings completely fails to teach any methods relevant to Applicants' claimed invention. Applicants further disagree with other statements in the Office Action, as follows.

The office action states "Cummings discloses that low serum level of vitamin D compounds leads to bone loss disorders (column 2, lines 43-45). In fact, these lines do not state this, but instead state the following:

> "Post menopausal subject" refers to women in the period of life after menopause. Subjects afflicted with post-menopausal symptoms include women after menopause who exhibit any of the foregoing physical conditions after menopause, and particularly women after menopause who have exhibited decreased fone mineral density, in the vertebrae, hip or other site or who have experienced wither vertebral or hip fracture."

The statement in the Office Action clearly is not factually based upon the cited passage.

With respect to the proposed combination of Cummings and Knutson, Applicants note that even if the examiner has correctly analyzed the teachings of

Knutson, Knutson does not compensate for the deficiencies pointed out above with respect to Cummings.

Thus, the rejection is insufficient to render Applicants' invention as presently claimed obvious. The rejection should therefore be withdrawn.

Conclusion

Applicants respectfully submit that the subject application is in condition for allowance and prompt allowance thereof is respectfully requested.

The examiner is urged to telephone the undersigned at 847 937-4558 to facilitate resolution of any remaining issues so that the subject application can be processed for allowance promptly.

23492

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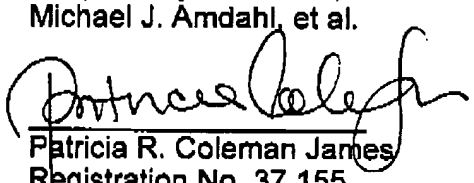
Respectfully submitted,
Michael J. Amdahl, et al.



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PTO-90C (Rev. 10/03)

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Commissioner for Patents

The reply filed on February 03, 2005 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Claims 1 and 7 are indicated as being "(Currently Amended)", however, Applicant does not provide underlining markings for all of the amendments in the claims. For example, claims 1 and 7 have the steps as "a.", "b.", etc.; while said steps have been previously recited as "a)", "b)", etc. in the claims, filed October 12, 2001. It is noted that Applicant has amended the recitation of the steps without providing underlining markings to indicate said amendments, which is improper (See MPEP 714 [R-2]). It is noted that the use of internal periods such as "a." is improper because the MPEP states that each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations (See MPEP 608.01(m) [R-2]). Further, Applicant uses single brackets in claim 1, line 2, claim 6, lines 1 and 3, claim 7, line 2, and claim 10, line 2 and 3. The MPEP states that double brackets may be used to indicate deleted characters that are five or fewer consecutive characters (See MPEP §714 [R-2]). Therefore, it is not clear whether Applicant intends to use the single brackets to indicate deletion, or the single brackets are part of the claim language.

See 37 CFR 1.111. Since the above-mentioned reply appears to be bona fide, applicant is given ONE (1) MONTH or THIRTY (30) DAYS from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly
4/27/05 /CDL

Ardin H. Marschel 4/30/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER